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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
09/914,795	09/05/2001	Gunther Berndl	49727	4232
<sup>26474</sup> NOVAK DRU	7590 06/04/2007 CE DELUCA & QUIG		EXAMINER	
1300 EYE STE	1300 EYE STREET NW SUITE 1000 WEST TOWER WASHINGTON, DC 20005		LANDAU, SHARMILA GOLLAMUDI	
			ART UNIT	PAPER NUMBER
			1616	
	·		MAIL DATE	DELIVERY MODE
			06/04/2007	n a pro

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.



## UNITED STATES DEPARTMENT OF COMMERCE U.S. Patent and Trademark Office

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APPLICATION NO./ CONTROL NO.	FILING DATE	FIRST NAMED INVENTOR / PATENT IN REEXAMINATION	ATTORNEY DOCKET NO.
00014705	0/5/01	DEDNINI ET AI	40727

09914795 9/5/01

BERNDL ET AL.

49/2/

NOVAK DRUCE DELUCA & QUIGG, LLP 1300 EYE STREET NW SUITE 1000 WEST TOWER WASHINGTON, DC 20005 EXAMINER
Sharmila Gollamudi Landau

ART UNIT PAPER

1616

20070529

DATE MAILED:

Please find below and/or attached an Office communication concerning this application or proceeding.

**Commissioner for Patents** 

See attached sheet.

Sharmila Gollamudi Landau Primary Examiner

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Art Unit: 1616

Application/Control Number: 09/914,795

Art Unit: 1616

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The reply filed on 4/20/07 is not fully responsive to the prior Office Action because of the following omission(s) or matter(s): Applicant has not responded to <u>any</u> of rejections of record. <u>See</u> 37 CFR 1.111. Since the above-mentioned reply appears to be *bona fide*, applicant is given **ONE** (1) **MONTH or THIRTY** (30) **DAYS** from the mailing date of this notice, whichever is longer, within which to supply the omission or correction in order to avoid abandonment. EXTENSIONS OF THIS TIME PERIOD MAY BE GRANTED UNDER 37 CFR 1.136(a).

It is noted that applicant has requested the examiner withdrawn the non-final office action mailed 4/16/07 on the grounds that the Office Action contained an incomplete sentence.

Applicant argues that MPEP 707.07(d) states that, "[w]here a claim is refused for any reason relating to the merits thereof it should be "rejected" and the ground of rejection fully and clearly stated .... .1 Thus, applicant argues that the incomplete phrase on page 9, at line 19 of the Office action renders the entire rejection unclear.

The examiner firstly points out that this incomplete sentence appears under the section "Response to Arguments" and not under the "Statutory Rejection" section, i.e. the section containing the statutory basis for the rejection, the claims rejected, and the grounds for rejecting the claims. MPEP 707.07(d) mandates that the examiner set forth the *rejection* clearly. The "Response to Arguments" section and the "Statutory Rejection" section are <u>not</u> equivalent. In accordance to MPEP 707.07 (d), the examiner fully and clearly stated the rejection on pages 3 to 8. Moreover, page 6 of the *rejection* clearly sets forth the reasons to manipulate the weight percent of the polymeric binder.

It would have been obvious at the time the invention was made to combine the teachings of Baert et al and Stella et al and utilize the a polymer as the additive in Baert's process.

Application/Control Number: 09/914,795

Art Unit: 1616

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Firstly, one would have been motivated to do so since Stella teaches the use of a rate controlling modifiers, such as exemplified HPMC, control the release rate of the active to provide for a delayed, targeted, sustained, etc. dosage form. Therefore, one would have been motivated to add a polymer such as instant polymer in the instant amount, to modify the release rate of the dosage form. Further, it would have been obvious to utilize the polymer in the instant weight percent since Stella teaches the concentration of the rate controlling polymer determines the release rate. Therefore, depending on the release rate of the active, a skilled artisan would have been motivated to adjust the concentration accordingly. For instance, if one desired a slow release rate, a skilled artisan would have been motivated to add 50% of the polymer.

Thus, the examiner has complied with the MPEP 707.07(d) wherein the examiner has provided 1) the statutory basis for the rejection, 2) the claims rejected, 3) and the grounds for rejecting the claims.

Moreover, the incomplete sentence that appears on page 9, would have merely re-stated the examiner's reasoning on page 6, i.e. "With regard to the weight percent, the examiner points out that Stella teaches the use of rate controlling modifiers to control the release rate of the active to provide for a delayed, targeted, sustained, etc. dosage form. Thus if one desired a slow rate, a skilled artisan would have been motivated to add 50% of the rate-controlling polymer."

Lastly, the examiner points out that applicant substantially amended the claims, which required new grounds of rejection. Thus, the rejection applicant is referring to, did not require a "Response to Arguments" section since it was a new rejection.

It is the examiner's position that the rejection is clear, complete, and the rejection is capable of being understood in its entirety. Therefore, a new Non-Final Office Action, re-starting the time period, will <u>not</u> be issued.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila Gollamudi Landau whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

Application/Control Number: 09/914,795

Art Unit: 1616

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Page 4

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Sharmila Gollamudi Landau

Primary Examiner
Art Unit 1616

**SGL**